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Twenty-first day of January 2005

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Cochlear Limited

PROVISIONAL SPECIFICATION

Invention Title:

Parametric fitting of a cochlear implant

The invention is described in the following statement:

Field of the Invention

The present invention relates to an improved method of clinically fitting a cochlear implant to a recipient to satisfy the recipient's hearing needs.

Description of the Prior Art

Cochlear implants have been developed to assist people who are profoundly deaf or severely hearing impaired, by enabling them to experience hearing sensation representative of the natural hearing sensation. In most such cases, these individuals have an absence of or destruction of the hair cells in the cochlea which naturally transduce acoustic signals into nerve impulses which are interpreted by the brain as sound. The cochlear implant therefore bypasses the hair cells to directly deliver electrical stimulation to the auditory nerves with this electrical stimulation being representative of the sound.

Cochlear implants have traditionally consisted of two parts, an external speech processor unit and an implanted receiver/stimulator unit. The external speech processor unit has been worn on the body of the user and its main purpose has been to detect the external sound using a microphone and convert the detected sound into a coded signal through an appropriate speech processing strategy.

This coded signal is then sent to the receiver/stimulator unit which is implanted in the mastoid bone of the user, via a transcutaneous link. The receiver/stimulator unit then processes this coded signal into a series of stimulation sequences which are then applied directly to the auditory verve via a series of electrodes positioned within the cochlea, proximal to the modiolus of the cochlea.

With improvements in technology it is possible that the external speech processor and implanted stimulator unit may be combined to produce a totally implantable cochlear implant unit that is capable for operating, at least for a portion of time, without the need for any external device. In such a device, a microphone would be implanted within the body of the user, for example in the

ear canal or within the stimulator unit, and sounds would be detected and directly processed by a speech processor within the stimulator unit, with the subsequent stimulation signals delivered without the need for any transcutaneous transmission of signals. Such a device would, however, still have the capability to communicate with an external device when necessary, particularly for program upgrades and/or implant interrogation, and if the operating parameters of the device required alteration.

Typically, following the surgical implantation of a cochlear implant, the recipient must have the implant fitted or customised to conform with the specific demands of that recipient. This procedure is often referred to as "mapping" and is the term given to the process of measuring and controlling the amount of electrical current delivered to the cochlea. This process leads to the creation of a program or map that ensures stimulation from the implant provides a patient with comfortable and useful auditory perception, and is essential in ensuring that the recipient receives maximum benefit from the cochlear implant. As the implant system is designed to present acoustic information, in particular speech, to a patient in a useable form, the initial aim of the mapping process is to optimise the information provided for a particular patient.

A fundamental aspect of this procedure is the collection and determination of recipient specific parameters such as threshold levels (known as T levels) and maximum comfort levels (known as C levels) for each stimulation channel. It should be stressed that it is not the particular T or C levels that matter or whether they conform precisely to a psychophysical definition, but how well the recipient hears and understands detected speech or sounds. As speech will invariably sound different through the implant, the recipient's subjective reactions can be disappointing at first, and it is important not to let the subjective reactions override other considerations in speech processor mapping.

It has been found that constant changes to a recipient's map do not allow recipients to adapt to a particular configuration thereby leading to recipient frustration with their implant. In this case, it is the role of the clinician to have confidence that the implant system provides useful information to the recipient

and to not make radical changes to the map unless there is a clear reason to do so.

Conventionally, this step of determining T and C levels is manually performed by applying stimulation pulses for each electrode channel of the implant and receiving an indication from the implant recipient as to the level and comfort of the resulting sound. The T level is defined as the level at which the recipient first identifies sound sensation, and is the lowest level at which the recipient hears the stimulus every time it is presented. The T level is often determined by passing the recipient's hearing threshold twice using an ascending method and determining the level at which the recipient experiences sound. The C level sets the maximum allowable stimulation level for each electrode and is defined as the maximum stimulation level that does not produce an uncomfortable loudness sensation for the recipient. In setting and establishing the C levels, it is usual to instruct the recipient to indicate a level which is "as loud as would be comfortable for long periods". The C levels affect how speech sounds to the patient more than T levels as most of the acoustic speech signal will be mapped onto the top 20% of the T and C level range.

Establishing and setting T and C levels for each electrode channel in a mapping process is an important aspect of a fitting session for a cochlear implant. For implants with a large number of electrode channels for stimulation, this process is quite time consuming and rather subjective as it relies heavily on the recipient's subjective impression of the stimulation rather than any specific measurement. This aspect is further complicated in the case of very young children, children with multiple handicapping conditions and/or are developmentally delayed, and pre-lingually or congenitally deaf patients who are unable to supply an accurate impression of the resultant hearing sensation. In these cases, the fitting of the implant may be non-optimal. In such cases an incorrectly fitted implant will result in the recipient not receiving optimum benefit from the implant and in the cases of children may directly hamper the speech and hearing development of the child.

The present invention is directed to a process of mapping the operation of a cochlear implant that address the problems described herein.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

In order to improve the mapping process and decrease the time taken in developing a useful map for a recipient, there is a need to manipulate T and C levels more effectively than has previously been the case. In the past, T and C levels have been manipulated on a one-by-one basis and not globally, taking into consideration the interaction between channels, resulting in there being a number of degrees of freedom in the manipulation of T and C levels. The present invention aims to reduce the degrees of freedom associated with setting the T and C levels for a recipient and to concentrate on manipulating these levels parametrically, based upon objective measures, statistical analysis of recipient maps and from other such observations or theoretical considerations.

The present invention preferably provides a method for fitting a speech processor and implantable cochlear stimulator to a particular recipient in a quicker and more effective manner than has historically been the case.

In accordance with one aspect, the present invention is a method of fitting an auditory stimulation system having a plurality of electrodes to a recipient, the method comprising the steps of:

establishing an initial current level profile representative of a current level setting spanning across at least some of the plurality of electrode channels; and

adjusting parameters of the initial current level profile in the presence of a stimulation signal.

In a further embodiment of this aspect, the method can further comprise a step of:

determining the desired parameters representative of an optimum current level profile corresponding to a recipient's threshold and/or maximum comfort current level profile.

According to a second aspect, the present invention is a programming apparatus adapted to be interfaced with an auditory stimulation system having a plurality of electrodes and so allow manipulation of the threshold (T) and comfort (C) levels of the system, the programming apparatus comprising:

a graphical display means adapted to display a graphical representation of the current profile of the electrode array; and

means for adjusting the current level profile.

In a preferred embodiment, the auditory stimulation system comprises a cochlear implant system. The cochlear implant system preferably utilises an electrode array to deliver electrical stimulations to the cochlear of a recipient. In one embodiment, the array comprises 22 intracochlear electrodes and at least one extracochlear electrode.

By manipulating the parameters of a current level profile spanning preferably all electrodes of the electrode array, there is no need to determine threshold and comfort level currents for each individual electrode in the array of an implant following implantation in the recipient. Instead, manipulation is preferably applied to the entire profile resulting in a greatly reduced amount of psychophysical measurements required and a programming/fitting procedure that is more recipient friendly, more time efficient and more cost effective.

Preferably, the step of establishing an initial current level profile includes a step of obtaining measurements of the evoked compound action potential

(ECAP) thresholds for each or a number of the electrodes and establishing a current level profile based upon these measurements. In another embodiment, the initial current level profile is preferably established from measurements of the ECAP thresholds for at least one electrode of the auditory stimulation system, with the full profile being interpolated from such measurements.

In another embodiment, the step of establishing an initial current level profile includes the step of performing a statistical analysis of patient mapping data over a number of recipients and using this analysis to form an initial current level profile for a particular recipient.

In yet another embodiment, the step of establishing an initial current level profile includes the step of performing a number of psychophysical and/or electrophysiological measurements of the recipient in combination with statistical analysis of recipient mapping data over a number of recipients to determine a suitable initial current level profile for a particular recipient.

The initially determined suitable current level profile is preferably represented on the graphical display means of the programming apparatus to allow ready determination by a clinician of the current profile of the array.

The step of adjusting the overall parameters of the initial current level profile preferably includes adding/subtracting a fixed or derived amount of current level from each individual electrode in the profile. This parameter adjustment is referred to as a "shift" manipulation, and has the effect of moving the profile up or down in a vertical direction on a graph plotting current level against electrode number.

By "shifting" the profile "up", either a fixed amount of current is added to the current level of each individual electrode in the profile (linear shift), or an individually derived current level is added to each electrode (non-linear shift), thereby increasing the amount of current delivered by the electrodes when operated with that particular profile.

By "shifting" the profile "down", either a fixed amount of current is subtracted from the current level of each individual electrode in the profile

(linear shift), or an individually derived current level is subtracted from each electrode (non-linear shift), thereby decreasing the amount of current delivered by the electrodes when operated with that particular profile.

The overall parameters of the initial current profile can also be adjusted by adding an electrode specific derived amount of current level to a subset of electrodes in the profile and subtracting an electrode specific derived amount of current level from the remaining electrodes. This parameter adjustment is preferably referred to as a "tilt" manipulation, and has the effect of tilting the profile clockwise or anti-clockwise on a graph plotting current level against electrode. In a preferred embodiment, the "tilt" manipulation may be performed by using at least one electrode, for example electrode 12 of said plurality of electrodes, as a pivot point and for each electrode 1-11 the individual current levels of each electrode is decreased by a varying percentage of a fixed amount of current, and for each electrode 13-22, the current level for each electrode is increased by a varying percentage of a fixed amount of current, or vice versa. In this regard and where the electrode array is adapted to be positioned within the cochlea, the electrodes positioned in the apical region may have their current levels increased and those within the basal region may have their current levels decreased, or vice versa. The amount of current level to be added/subtracted from the electrode can be a function solely depending on the distance of the electrode in question to the pivot point (linear tilt) or can have a more complex dependency, e.g. depend from a separate "tilt profile" in addition (non-linear tilt).

The overall parameters of the initial current level profile can also be adjusted by adding/subtracting a derived amount of current level from each individual electrode in the profile in such a way as to bend the current level profile. This can be interpreted as a profile manipulation using 2 pivot points, which might be allocated but are not limited to the most basal and most apical electrode. These pivot points might even be situated outside the actual range of electrodes available. This parameter adjustment can be referred to as a "curvature" manipulation and has the effect of causing the profile to curve or change shape on a graph plotting current level against electrode. The "curvature" can be achieved in a linear and non-linear manner, as described above. The derived values used for the non-linear manipulations can stem

from statistical analysis, such as vector analysis of available clinical data. They can be influenced by several factors, such as the actual starting level, whether it is a T or a C level, the implant and electrode type used or the coding strategy applied. Other sources of influence and any combination of factors can be used to calculate the derived data.

Other parameter manipulations suitable to adjusting the current level profile are also included within the scope of the present invention.

In a preferred embodiment, the step of adjusting the overall parameters of the initial current level profile can include any one or combination of a "shift" manipulation, a "tilt" manipulation and/or a "curvature" manipulation.

Adjustment of the profile is preferably performed through a clinician interface that allows the current profile of the electrode array to be adjusted in the manner described herein. In one embodiment, a software package can be run on a computer, with the software package offering input means that allows the clinician to readily adjust the current profile of the array. The input means can comprise one or more of a mouse, joystick, roller ball, keyboard, or keypad, that allows the clinician to adjust the settings within the software package.

In a preferred embodiment, the overall parameters of the initial current level profile are adjusted in the presence of a broad band signal, preferably a live speech signal. In such a case, the implant delivers stimulation representative of the signal, in accordance with the current level profile. By adjusting the parameters of the current level profile the stimulation delivered by the implant varies, allowing the stimulation signal to be optimised in terms of patient threshold and maximum current levels.

The method and apparatus according to the present invention present a number of potential advantages, over existing techniques. In particular, it is envisaged that fewer psychophysical measurements will be needed to be prepare a map for a particular recipient. The ability to use live sounds is also potentially more interesting for small children than arbitrary stimuli used to date.

Brief Description of the Drawings

Embodiments of the invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a graphical example of a typical recipient map generated by conventional mapping techniques;

Figure 2 is a graphical representation of a typical ECAP waveform showing negative (N1) and positive (P1) peaks;

Figure 3 is a graphical representation of the changes in ECAP as a function of the stimulus current level;

Figure 4 shows the ECAP growth function;

Figure 5 shows the relation ship between the average ECAP thresholds and the behavioural T and C levels for a group of 82 recipients using the Nucleus® 24 implant;

Figure 6 shows the relationship between the ECAP thresholds and the behavioural T and C levels from a recipient implanted with a Nucleus® 24 Contour™ implant;

Figure 7 is a flow chart of the method of the present invention;

Figure 8 shows the step of importing ECAP thresholds according to one embodiment of the present invention;

Figure 9 shows the step of interpolating the CL profile from the imported ECAP thresholds of Figure 8, according to an embodiment of the present invention;

Figure 10 shows complete ECAP thresholds used as an initial CL profile according to another embodiment of the present invention.;

Figure 11 shows the initial CL profile being shifted below the recipient's hearing threshold according to step 2 of Figure 7;

Figure 12 shows the CL profile representative of when a recipient can just hear live speech according to steps 3 and 4 of Figure 7;

Figure 13 shows the CL profile tilted a current level value of +5 according to step 5 of Figure 7;

Figure 14 shows the CL profile tilted a current level value of +10 according to step 5 of Figure 7;

Figure 15 shows the CL profile tilted a current level value of +15 according to step 5 of Figure 7;

Figure 16 shows the CL profile tilted a current level value of -5 according to step 5 of Figure 7;

Figure 17 shows the CL profile tilted a current level value of -10 according to step 5 of Figure 7; and

Figure 18 shows an example of an optimum T-level profile generated from the initial CL profile according to step 9 of Figure 7.

Preferred Mode of Carrying out the Invention

The following description is directed to a cochlear implant system having an electrode array, in particular an array having twenty two intracochlear electrodes. It will be appreciated that the invention has potential applicability to any auditory stimulation system utilising an electrode array and in particular to electrode arrays comprising less or more electrodes than that described herein.

In order to better understand the present invention, it is appropriate to firstly consider one method of programming a cochlear implant and creating a map which enables the speech processor to output data in a form which can be decoded by the receiver/stimulator.

As a map is a complete set of instructions for the speech processor which includes the minimum and maximum stimulation levels for each electrode, conventional programming methods have required the clinician creating the map for the recipient of the implant, to measure T and C levels for each electrode, for the stimulation mode and speech processing strategy chosen for the recipient. This process requires an experienced clinician/audiologist to present a stimulus, usually a fixed phase biphasic pulse at a fixed rate and duration, to each electrode of the recipient's implanted electrode array. The clinician/audiologist then asks the subject to estimate the lowest level at which that stimulus can be detected (T level) and the level judged by the recipient as being the upper limit of comfort (C level). This process is repeated for all of the electrodes, for example, all 22 electrode channels in a current Nucleus® model device as manufactured by the present applicant, until a map is created which includes T and C levels for each electrode that can receive stimulation pulses. It has been found that initial estimates of the T and C levels as determined by the clinician/audiologist working in conjunction with the recipient (where possible) using the conventional method are variable and may take months to stabilise. As such, it is easy to appreciate that the conventional programming method is a laborious task requiring much experience and expertise by the clinician and relying on good feedback from the recipient to create the most optimal map.

Figure 1 shows a typical recipient map which may be generated by a clinician during such a mapping session. This map has been generated using a software package developed by the present applicant to assist the clinician by providing an interface that is easy for the clinician to manipulate and visualise. The horizontal sections numbered 1-22 (along the top) indicate the electrode number along the intracochlear array of the implant, and the vertical axis represents current level for each electrode in the array. This software package is run on a computer that outputs signals set by the software package through an interface. The interface is adapted to connect to the speech processor and allow transmission of signals from the computer to the processing control system of the speech processor which in turn outputs stimulation signals via the transcutaneous radio frequency (RF) link to the implanted receiver/stimulator unit of the system.

As is shown in this particular example, the upper vertical limit for each channel is the maximum comfort level (C level) which represents for that particular electrode, the maximum amount of current which can be delivered to deliver a sensation to the recipient at a loudness level which is just tolerable to that recipient. The lower vertical limit for each electrode is the threshold level (T level) which represents the amount of current which can be delivered to that electrode to produce a sensation that is just audible to the recipient. In this particular example, the T and C levels for a number of electrodes are specifically shown, and in use all sounds detected are mapped between these 2 levels to produce the equivalent sound sensation to the recipient.

In the software package as shown in Figure 1, the T and C levels can be altered up or down by the clinician using appropriate controls on the computer so leading to altered signals being sent to the speech processor which in turn adjusts the stimulation signals output by the electrode array. This alteration can be made with feedback from the recipient indicating whether the sensation is either too loud or just audible.

Whilst the conventional mapping techniques are time consuming and arduous for both the clinician and the recipient, there has to date been no reliable alternative implemented on a wide scale. However, with an increased understanding of the response of nerves to electrical stimulation, there has been research into how this increased understanding can assist in understanding the parameters associated with delivering electrical stimulation, and this has suggested possible new ways to improve the conventional mapping process.

For a number of years it has been possible to record the electrically evoked auditory brain stem response (EABR) in cochlear implant recipients and a number of studies have been conducted which have attempted to correlate EABR thresholds to mapped threshold and/or comfort levels. Such EABR measurements have required the use of surface recording electrodes and the complications and lengthy nature of this measuring process have hindered this technique from becoming routinely adopted. Still further, the recipient being

assessed has often had to be asleep or heavily sedated to avoid contaminated measurements from being recorded by the recording electrodes.

It is only more recently that a simple and more direct way to assess auditory nerve function in cochlear implants has been possible, by measuring the electrically evoked compound action potential (ECAP). This potential reflects the synchronised response of peripheral auditory nerves delivered by an intracochlear electrode, and the response typically resembles a waveform having an initial negative peak followed by a positive peak. Initially, such ECAP measurements could only be obtained intraoperatively through the use of a temporary intracochlear electrode array, or with cochlear implant recipients having a device with a percutaneous plug. In such cases, the ability to perform such measurements was only done experimentally, and as special instances had to be set up to allow such measurements to be taken, it was not possible to obtain such results for everyday use.

Recent developments undertaken by the present applicant have allowed for a quick and non-invasive method for recording the ECAP of the peripheral auditory nerves *in situ*, without the need for dedicated devices or plugs. Such a method has been designed into the conventional cochlear implant system to provide an additional feature of the system which can be utilised to take such measurements. The applicant's Nucleus® 24 model cochlear implants were the first implant system which such capabilities, and only now are the benefits of such a feature becoming fully realised.

The feature for recording the ECAPs in the Nucleus® 24 model device is known as Neural Response Telemetry (NRT) and whilst this application focuses on the NRT feature, it should be appreciated that this invention will be also applicable to other such methods of recording ECAPs, and hence should not be limited to use with the specific NRT feature.

In the mentioned feature, the bi-directional telemetry system that is present in the cochlear implant is used to measure the ECAP of the recipient's auditory nerve. Dedicated ECAP measurement software communicates with the implanted receiver/stimulator unit via the speech processor and RF link and biphasic current pulses are delivered to a single intracochlear electrode of the

array. The resulting ECAP is measured from a neighbouring electrode, amplified, encoded and sent back to the speech processor via the RF link. The data is then analysed using the speech processor and the dedicated ECAP measurement software, with the software then presenting the results in a manner easily interpreted by a clinician or implant specialist. As mentioned previously, in such a system the ECAP measurement can be taken without the need of any extra equipment, and therefore has considerable advantages over other evoked potential measures, such as the electrically evoked auditory brainstem response (EABR).

US Patent No. 5,758,651 describes one system and apparatus for recovering ECAP data from a cochlear implant. This system measures the neural response to the electrical stimulation by using the stimulus array to not only apply the stimulation but to also detect and receive the response. In this system the array used to stimulate and collect information is a standard intra-cochlear and/or extra-cochlear electrode array. Following the delivery of a stimulation pulse via chosen stimulus electrodes, all electrodes of the array are open circuited for a period of time prior to measurement of the induced neural response. The purpose of open circuiting all electrodes prior to measurement is to reduce the detected stimulus artefact measured with the ECAP nerve response.

Whilst the above system has proven useful in capturing and investigating evoked neural response in the cochlea, there are still a number of limitations intrinsic with this system, in particular in resolving the neural response from the stimulus artefact. This process has presented considerable difficulties, including problems such as the fact that the signals that are to be measured are extremely low level signals (down to the order of 10μV).

In cochlear implant applications in particular, a stimulus pulse is delivered with an amplitude typically in the range of 1V to 10V, which is orders of magnitude greater than the response that is to be measured resulting from this stimulation. Providing for a system that is firstly able to deliver a stimulus of sufficient amplitude and also to detect the elicited response of the nerves to that particular stimulation has therefore been problematic. Due to the nature of the neural response, the sensing system must be ready to record this response

within a short delay (preferably less than 50μs) after the trailing edge of the stimulus. In order to properly resolve the very small neural signal a large amplifier gain is required (typically of about 60dB to 80dB), however the neural signal is superimposed on a much larger artefact which distorts the actual measured signal considerably.

In order to overcome the above mentioned problems, the system as described in International Patent Application PCT/AU02/00500 was developed which delivers, subsequent to the first stimulus, a compensatory stimulus in order to counteract a residue charge distribution caused by the first stimulus. In this system, the artefacts associated with the stimulus could be addressed at the time of measuring the ECAPs, without the need for post measurement processing, thereby providing a more exact and useable measurement. This application also describes a method of optimising the parameters of the compensatory stimulus to take into account differences in the artefacts present, as may be the case from electrode to electrode or from recipient to recipient.

With improved methods of obtaining such measurements, there has been an interest in investigating ways to use this information in a clinical setting, rather than merely using the information merely to check that the electrodes are delivering stimulation. A number of initial studies have been undertaken to investigate potential clinical applications of such measurements, with a focus of such measurements being on determining whether the ECAP response can be used to aid in the programming of the cochlear implant speech processor. It is considered that such an application would be beneficial to clinicians and audiologists who work with very young children, where programming the speech processor presents significant challenges.

One such investigation was reported in Brown CJ, Hughes ML, Luk B, Abbas PJ, Wolaver A, Gervais J (2000) "*The Relationship Between EAP and EABR Thresholds and Levels Used to Program the Nucleus 24 Speech Processor: Data from Adults*" Ear & Hearing, 21, 151-163. In this investigation, ECAP thresholds were correlated with conventionally mapped T and C levels and it was shown that the correlation was not sufficiently strong to suggest that ECAP measurements could be directly used without some level of behavioural information.

This investigation suggested that whilst ECAP thresholds alone may not be strong predictors of either T or C levels, a combination of these results with a small amount of behavioural information may allow clinicians working with individuals with limited attention and/or response capabilities to be fitted with a cochlear implant with reasonable accuracy.

This finding was also consistent with a finding reported in Hughes ML, Brown CJ, Abbas PJ, Wolaver AA, Gervais JP (2000) "*Comparison of EAP Thresholds with MAP Levels in the Nucleus 24 Cochlear Implant: Data from Children*" Ear & Hearing, 21, 164-174. In this investigation, EAP thresholds were shown to fall between T and C levels for 18 out of 20 subjects tested. However, there existed a level of variability across recipients sufficient to make map threshold or comfort level predictions based solely on the objective EAP measures to have a significant error in most cases. Therefore, the EAP thresholds could provide an indication of "safe" levels of stimulation.

In order to understand this further, a typical ECAP waveform is shown in Figure 2, with the ECAP waveform consisting of an initial negative peak (labelled N1) followed by a positive peak (labelled P1). Using a recipient's Nucleus® 24 model implant, the ECAP measurement can be taken without the need for any extra equipment, as a neighbouring electrode to that which delivers the stimulation can be used to measure the ECAP, whereby the implant amplifies, encodes, and transmits the signal back to an external unit which then analyses the data with dedicated software, to enable the data to be easily interpreted by the clinician.

The N1 and P1 amplitude of the ECAP waveform vary with stimulating current as can be seen in Figure 3, with the amplitudes increasing with increases in stimulating current level. It is the amplitude growth function that can be used to estimate the ECAP threshold, and to quantify how the response changes with stimulus intensity. This is obtained via dedicated software that uses the ECAP amplitude, which is the difference (in μV) between the N1 and P1 amplitudes, which is evident in the graph in Figure 2. The ECAP threshold may be estimated visually by reviewing the amplitude growth series and selecting the electrical stimulation level which produces the smallest repeatable

N1 and P1 peaks in the waveform, or software can be used to extrapolate the ECAP threshold from the amplitude growth function. As is shown in Figure 4, the amplitude growth function is a plot of the ECAP amplitudes as a function of stimulus current levels and it has been found that a linear regression line can be fitted to the data to extrapolate the ECAP threshold and to define the slope of the function.

As mentioned above, the clinical value of the ECAP thresholds has been investigated, and it has been shown that there are some important relationships between the current levels of the ECAP thresholds and the behavioural T and C levels established by a clinician during a mapping procedure. The main relationships are that the ECAP thresholds correlate with the behavioural T and C levels, however the ECAP thresholds are not equal to the T or C levels but typically lie between the T and C levels, with the ECAP thresholds being typically audible to the recipient. This aspect is shown in Figure 5, where there is shown the average ECAP thresholds (T-NRT) and the behavioural T and C levels for a group of 82 recipients using the Nucleus® 24 model implant.

A further finding has been the fact that the profile of the ECAP threshold levels as a function of electrode number resembles the profiles of the T levels and to a lesser extent the C levels. This is shown in Figure 6, where the ECAP threshold profile (T-NRT) and the behavioural T and C levels are shown from a recipient implanted with a Nucleus® 24 model implant and Contour™ model array, which is manufactured by the present applicant.

With this understanding of how objective measurements can be taken which show the response of the peripheral auditory nerves to electrical stimulation delivered by the cochlear implant, there is a need to attempt to utilise these developments to make the fitting/programming session(s) for a cochlear implant more user friendly and clinically efficient.

An embodiment of the method according to the present invention is depicted by the flowchart in Figure 7. This method preferably provides a more efficient method of establishing and setting the T and C levels which are specific to each particular recipient.

The method of the present invention consists essentially of 2 steps which are used in the same manner to establish the T and C levels for a recipient. The starting point in all cases is to establish an initial current level profile across all electrode channels that can be manipulated by adjusting a few profile parameters to establish the T and C levels for that recipient. These parameters include, but are not limited to, vertical position shift, profile tilt and profile curvature of the current level profile.

The first step essentially moves each initial current level in the profile a series of increments until a target is met. This target would be either the fact that the threshold point has been determined, or that the maximum current level has been determined. Once this has occurred, the next step is to identify optimal values for other parameters describing the profile, to best achieve the target, namely that the threshold point has been achieved or that the maximum comfort point has been achieved.

The first step of the present invention is to establish a predefined initial current level (CL) profile (ie. step 1 of the flow chart). This profile gives a current level setting for each electrode channel and is the basis from which the final T and C level profiles are established. It is envisaged that more than one initial profile could be used, for example, one profile for setting T levels, another for setting C levels etc. As mentioned previously, this initial CL profile may be the result of measurements of the ECAP thresholds for each or a few of the electrodes, the result of a statistical analysis of patient mapping data over a number of subjects, or the result of a number of electrophysiological and/or psychophysics measurements in combination with statistical analysis, such as multiple regression. It is also conceivable that the initial CL profile may be a straight line.

As is shown in Figure 8, the initial CL profile may be derived from a small number of measured ECAP thresholds for specific electrodes, with the full profile being predicted for non-measured channels, similar to as is shown in Figure 9.

However, in a preferred embodiment, the ECAP thresholds for each channel would be used as the initial CL profile, as is shown in Figure 10.

Once the initial CL profile has been established in step 1, it is then preferably manipulated to establish appropriate T and C levels for the recipient. In step 2 of this process, the initial profile is shifted below the predicted desired target setting. In the case of setting the T-level profile, the initial CL profile would be shifted down to a level that would be below a recipient's threshold of hearing; for example, the maximum current level of the CL profile could be reduced to a current level of 80 with all other levels being relative to this.

In the case of setting the C level profile, the initial CL profile could be moved to any level that is below the maximum comfort level of the recipient as a starting point, for example, the previously identified threshold. A graphical example of this in relation to the setting of T levels can be seen in Figure 11, wherein the initial CL profile is shown as the thin line, and the dotted line represents the initial CL profile being shifted down below an arbitrary threshold level, ie. should the electrodes be stimulated to those current levels, the recipient would not experience sound sensation. It is this "shift" action that provides the first manipulation or adjustment of the CL profile.

In step 3, the recipient is presented with a broad band signal, for example a live speech sample, and the stimulation representative of this signal is delivered by the electrode array of the implant to the recipient within the constraints of the CL profile set by step 2. If the recipient does not detect the live speech, the CL profile is then shifted up or increased by a level step size (for example iterations of 5 current levels at a time) until the live speech is detected by the recipient, and what is considered as the "shift target" is met. Figure 12 is a graphical representation of this, showing the CL profile which has been shifted up a number of level steps from that shown in Figure 11, with this profile indicative of the point where the recipient indicates that they are detecting live speech.

At this stage in the process, the CL profile can be lowered one incremental step, and the profile manipulated by adjusting one parameter of a limited set of parameters, thereby changing the characteristics of the CL profile (ie step 5 in Fig. 7). In one embodiment, this manipulation is performed by applying a "tilt" manipulation to the profile, wherein a derived amount of current

level is added/subtracted to each individual current level value for the individual electrode of the electrode array. This manipulation literally "tilts" the profile as represented on a graph of current level against electrode number. That is, the profile is shifted down for high frequency channels and up for low frequency channels or vice versa. It is envisaged that the "tilt" may be linear or non-linear, e.g. derived from a tilt profile. A software package can automatically apply this "tilt" manipulation, by using, for example, electrode channel 12 as the pivot point. In the case of a linear tilt, for each channel from 22-13, the current level is increased by a varying percentage of fixed current levels, and for each channel from 11-1, the current levels are decreased by a varying percentage of fixed current levels, or vice versa. The use of other electrodes in the array as "pivot points" for the tilt manipulation can be envisaged.

In a preferred embodiment, the fixed current level may be 5. Figure 13 is a graphical example of such a CL profile manipulation indicative of a current level tilt of 5.

In this step of the process, the CL profile is manipulated by using the "tilt" value, until the live speech is no longer detected, ie. the target is not met. Then, step 3 as described above is repeated (shown in Figure 7 as step 6) until the recipient can again detect the live speech.

If no further shift/tilt combination meets the target criteria (i.e. sound detection in this example), then the current value for shift is the target shift value. The target shift value is that, which did not meet the target criterion and includes the highest CL amongst the profiles using the target shift and a tilt mot meeting the target. This CL profile is then saved in step 7.

Figures 14 –17 illustrate examples of different tilt values which may be used for steps 5 and 6, namely a fixed current level tilt of 10, 15, -5 or –10 may be used for these steps. Figure 18 represents a graphical example of an optimum threshold CL level achieved using this process, ie the initial CL profile which has been shifted down 10 current levels and tilted 10 current levels.

Having met the condition leading to step 7, the optimum CL profile is set as the T-level profile for use in the recipient's map. Alternatively, the process

could be continued by manipulating other profile parameters, such as profile curvature.

Whilst this process has been shown only in relation to setting the T levels, it can easily be used to set the C levels, with the only change required being the criterion of the "target". For setting the C levels, the "target" criterion is maximum comfort of sound perceived by the recipient, rather than sound detection, as is the case in setting the T levels.

The present invention therefore requires minimal psychophysics measurements using live voice, compared to many psychophysical measurements (roughly equivalent to twice the number of channels) using artificial stimuli as is the case in conventional mapping procedures. As a result, the present invention provides a programming/mapping procedure that is more patient friendly, and makes the fitting procedure, especially for small children, simpler, more time efficient and more cost effective then has historically been the case.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this twenty sixth day of June 2002

Cochlear Limited
Patent Attorneys for the Applicant:

F B RICE & CO

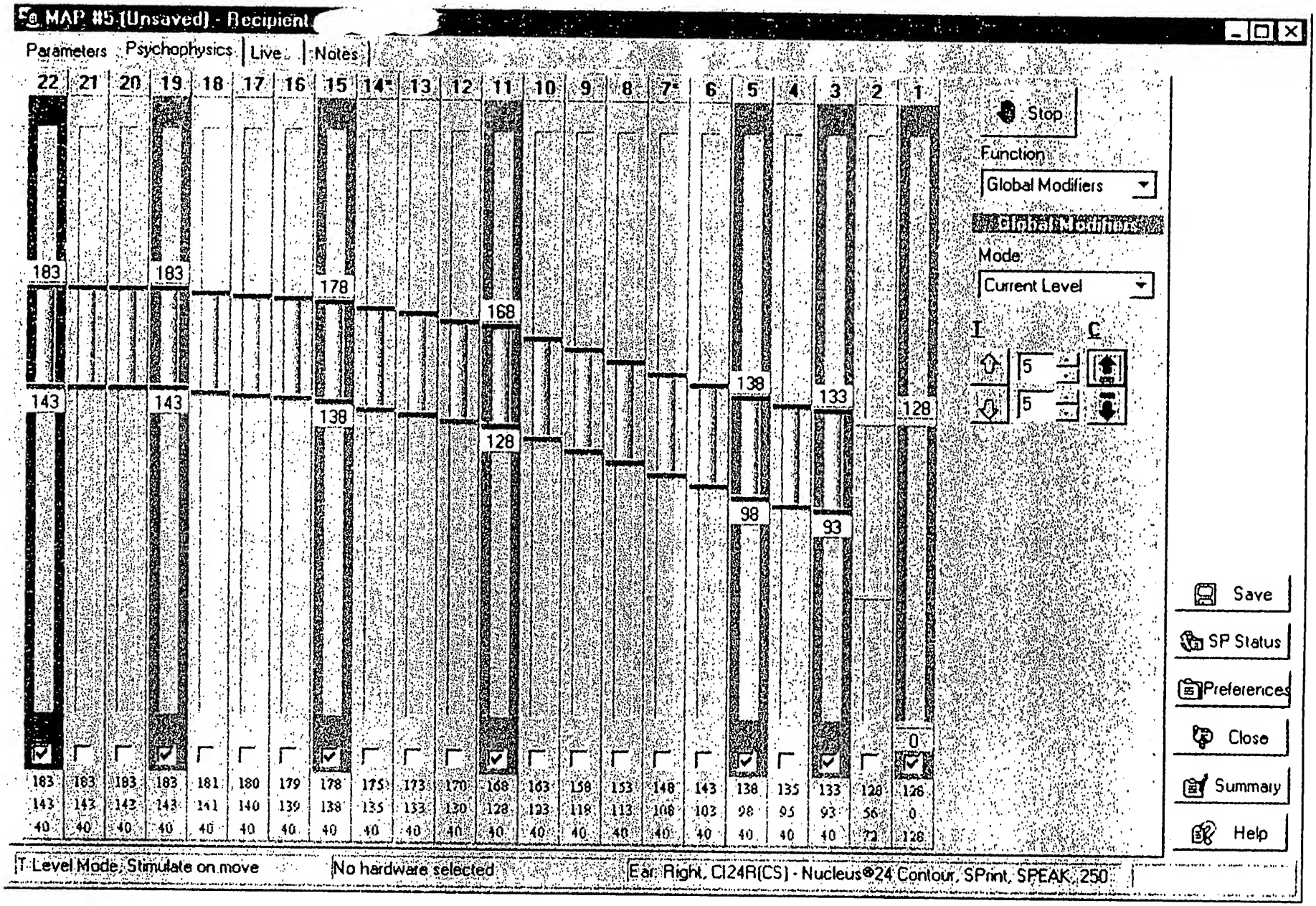

MAP #5 (Unsaved) - Recipient
Parameters
Psychophysics
Live
Notes
22 21 20 19 18 17 16 15 14 13 12 11 10 9 8 7 6 5 4 3 2 1
183 183 178 168 138 133 128
143 143 138 128 98 93 0
Stop
Function
Global Modifiers
Global Modifiers
Mode
Current Level
T
C
5
5
Save
SP Status
Preferences
Close
Summary
Help
T-Level Mode: Stimulate on move
No hardware selected
Ear: Right, CI24R(CS) - Nucleus®24 Contour, SPrint, SPEAK, 250

Figure 1

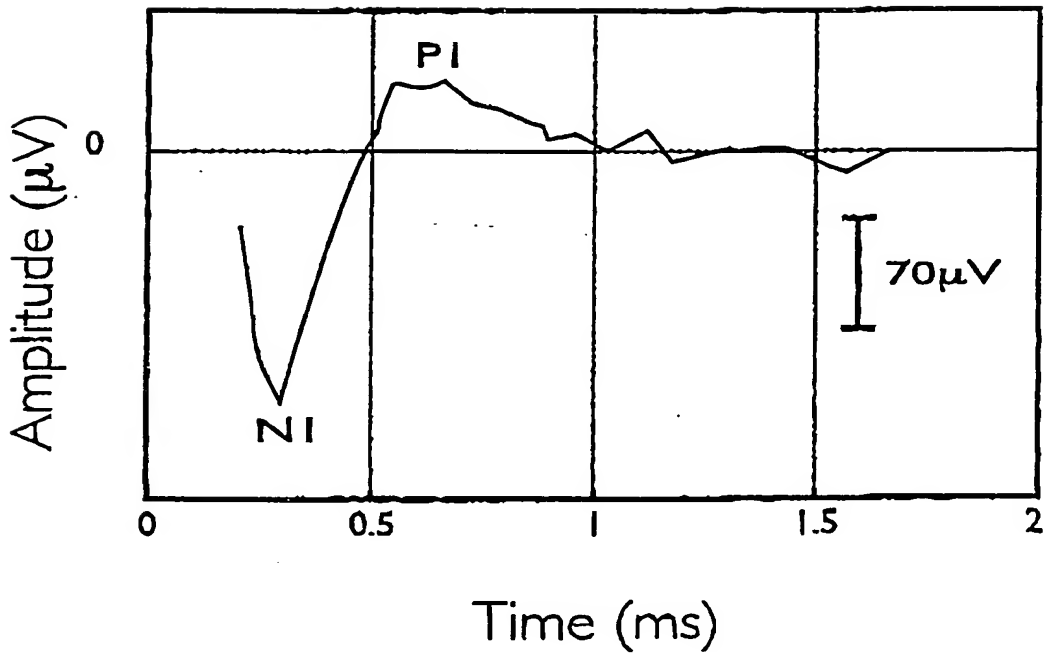


Figure 2

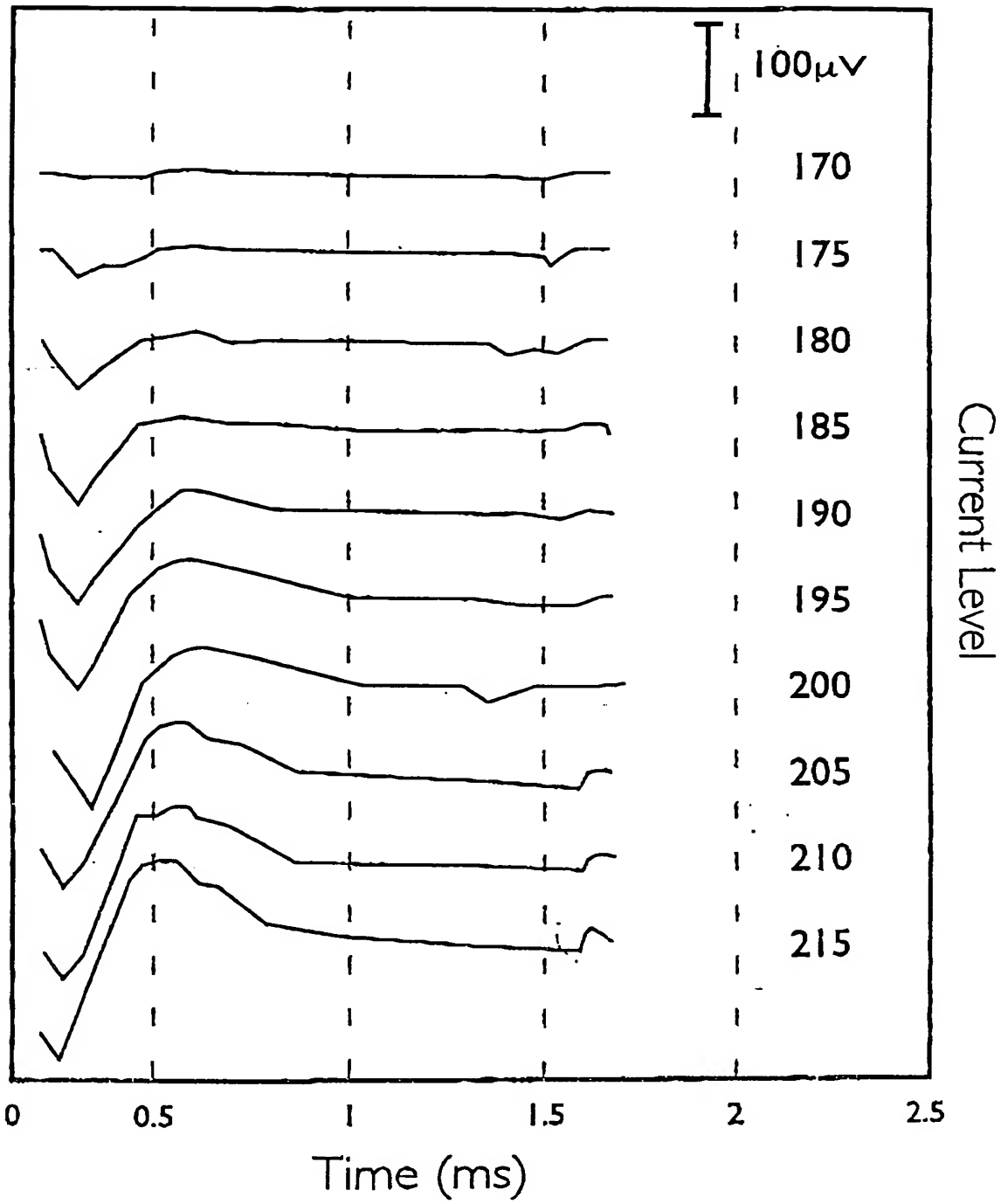

100μV
170
175
180
185
190
195
200
205
210
215
Current Level
0
0.5
1
1.5
2
2.5
Time (ms)

Figure 3

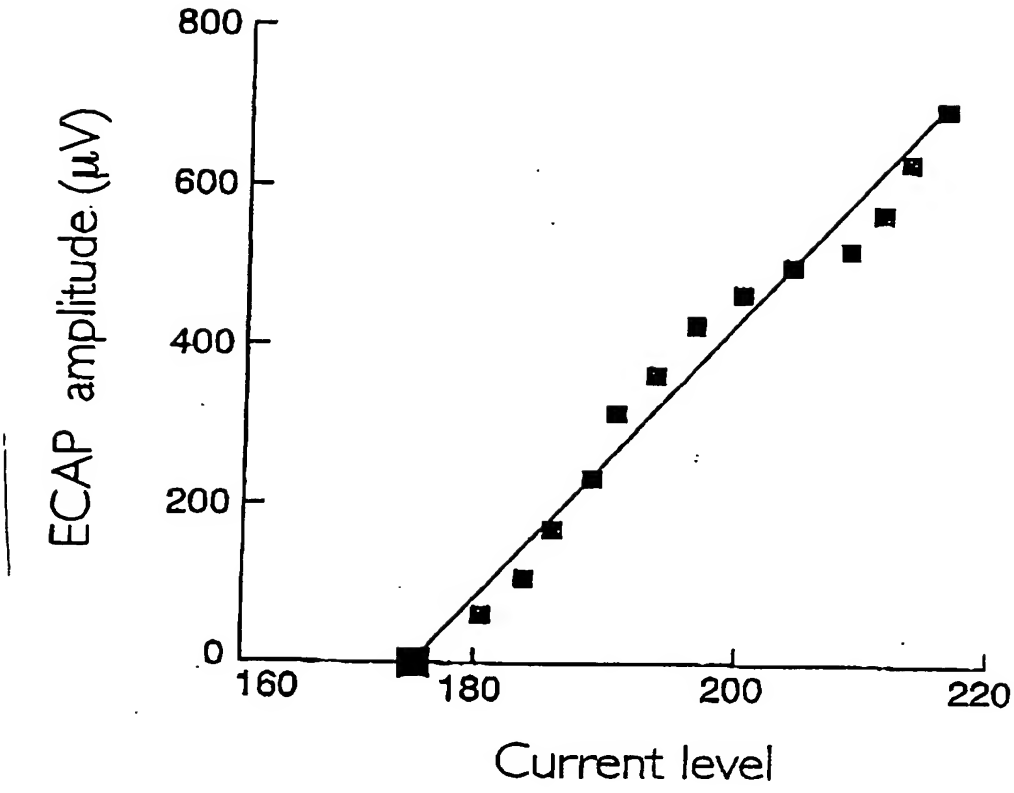

800
600
400
200
0
ECAP amplitude (μV)
160
180
200
220
Current level

Figure 4

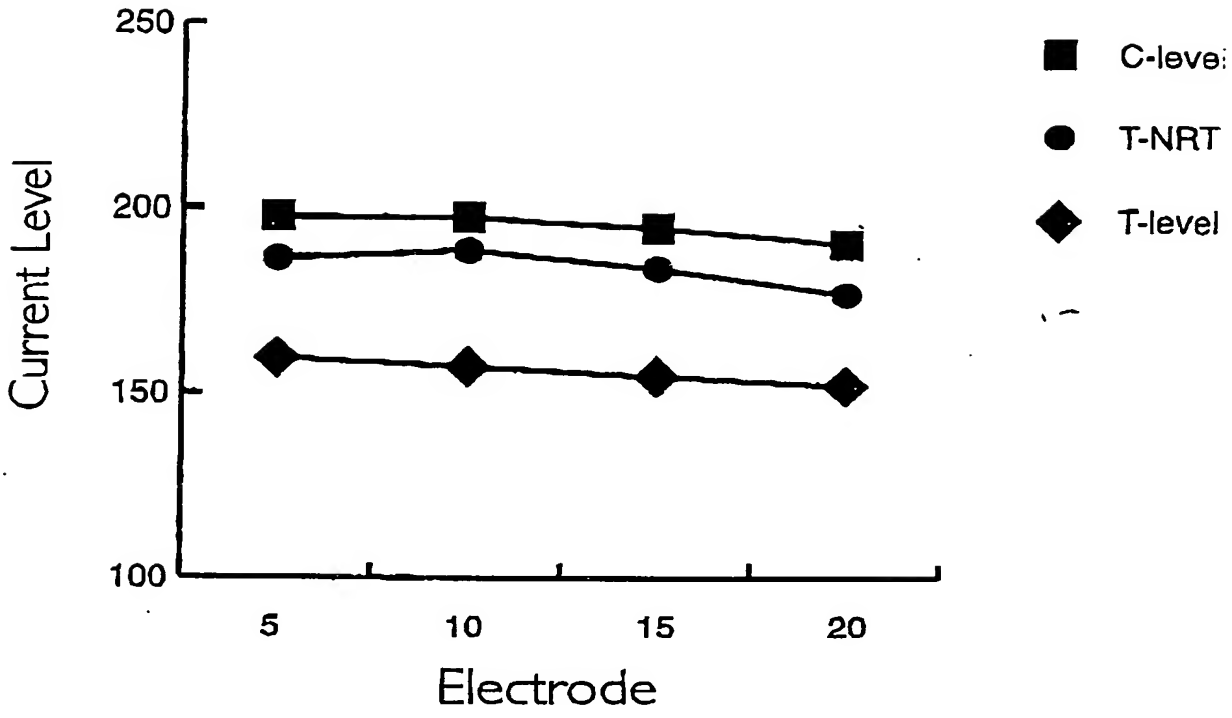

250
200
150
100
Current Level
5
10
15
20
Electrode
C-level
T-NRT
T-level

Figure 5

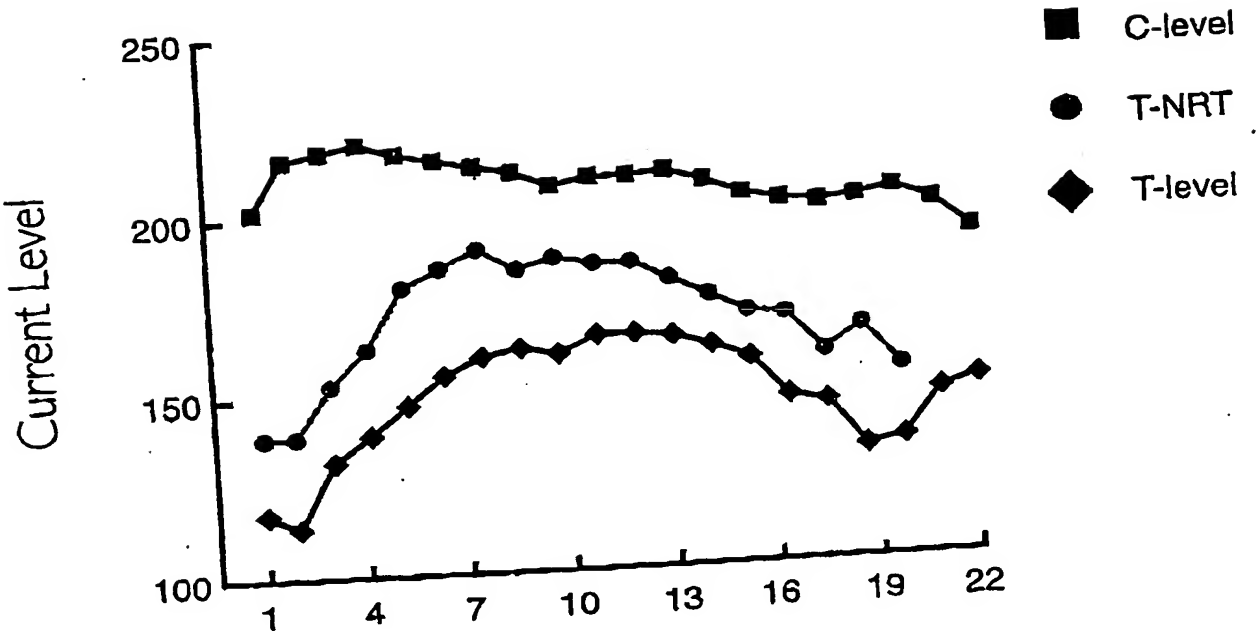

C-level
T-NRT
T-level
Current Level
250
200
150
100
1
4
7
10
13
16
19
22

Figure 6

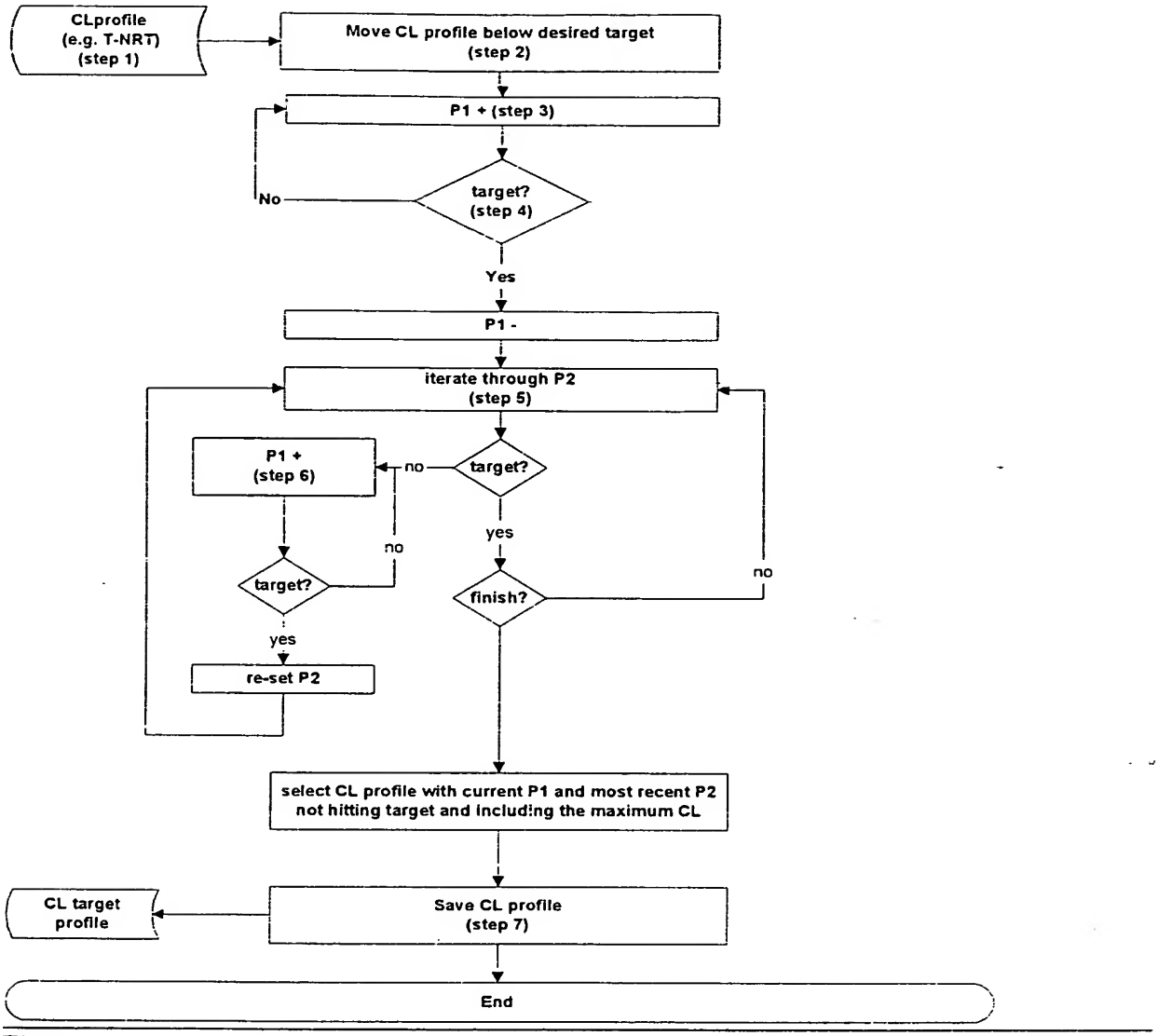
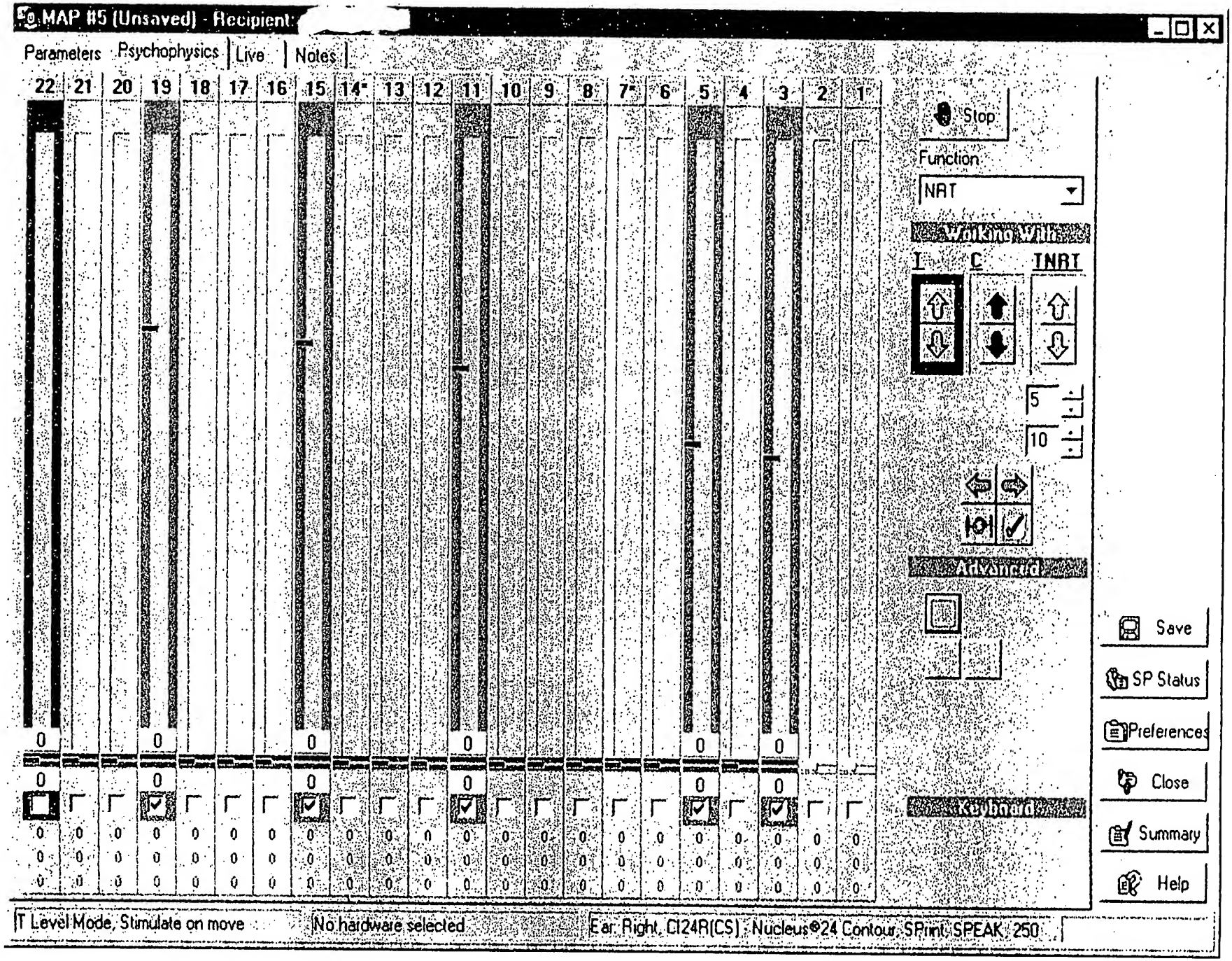
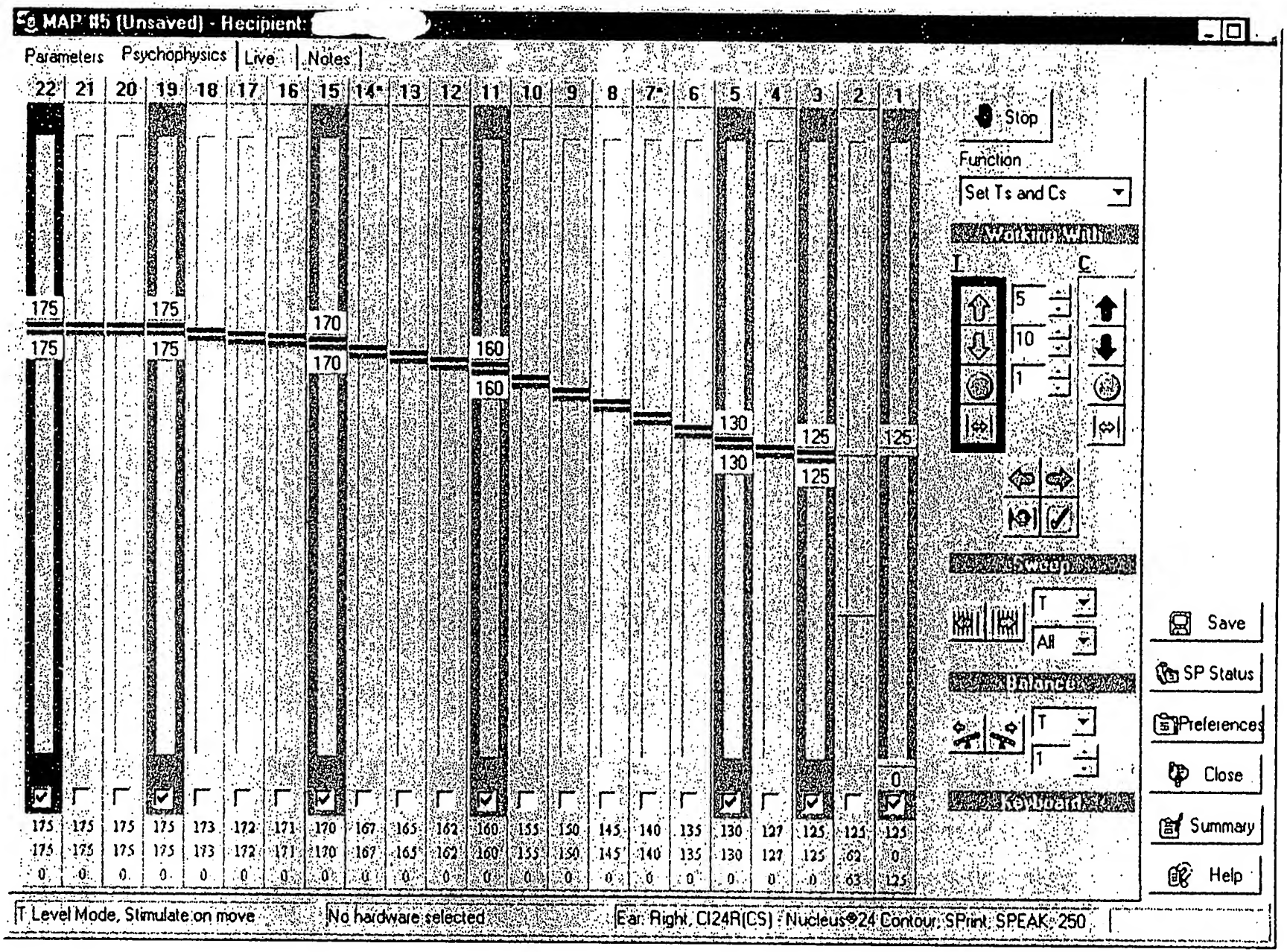

CLprofile
(e.g. T-NRT)
(step 1)
Move CL profile below desired target
(step 2)
P1 + (step 3)
target?
(step 4)
No
Yes
P1 -
iterate through P2
(step 5)
P1 +
(step 6)
no
target?
yes
no
target?
finish?
no
yes
re-set P2
select CL profile with current P1 and most recent P2
not hitting target and including the maximum CL
CL target
profile
Save CL profile
(step 7)
End

Fig.7


MAP #5 (Unsaved) - Recipient:
Parameters
Psychophysics
Live
Notes
22 21 20 19 18 17 16 15 14* 13 12 11 10 9 8 7* 6 5 4 3 2 1*
Stop
Function
NRT
Walking Width
I C INRT
5
10
Advanced
Keyboard
Save
SP Status
Preferences
Close
Summary
Help
T Level Mode, Stimulate on move
No hardware selected
Ear: Right, CI24R(CS) - Nucleus®24 Contour, SPrint, SPEAK, 250

- Figure 8


MAP #5 (Unsaved) - Recipient:
Parameters
Psychophysics
Live
Notes
22 21 20 19 18 17 16 15 14 13 12 11 10 9 8 7 6 5 4 3 2 1
175 175 175 175 173 172 171 170 167 165 162 160 155 150 145 140 135 130 127 125 125 125
175 175 175 175 173 172 171 170 167 165 162 160 155 150 145 140 135 130 127 125 62 0
0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 63 125
Stop
Function
Set Ts and Cs
Walking Width
I
C
5
10
1
Sweep
T
All
Balance
T
1
Keyboard
Save
SP Status
Preferences
Close
Summary
Help
T Level Mode, Stimulate on move
No hardware selected
Ear: Right, CI24R(CS) - Nucleus®24 Contour, SPrint, SPEAK, 250

- Figure 9

FIGURE 10

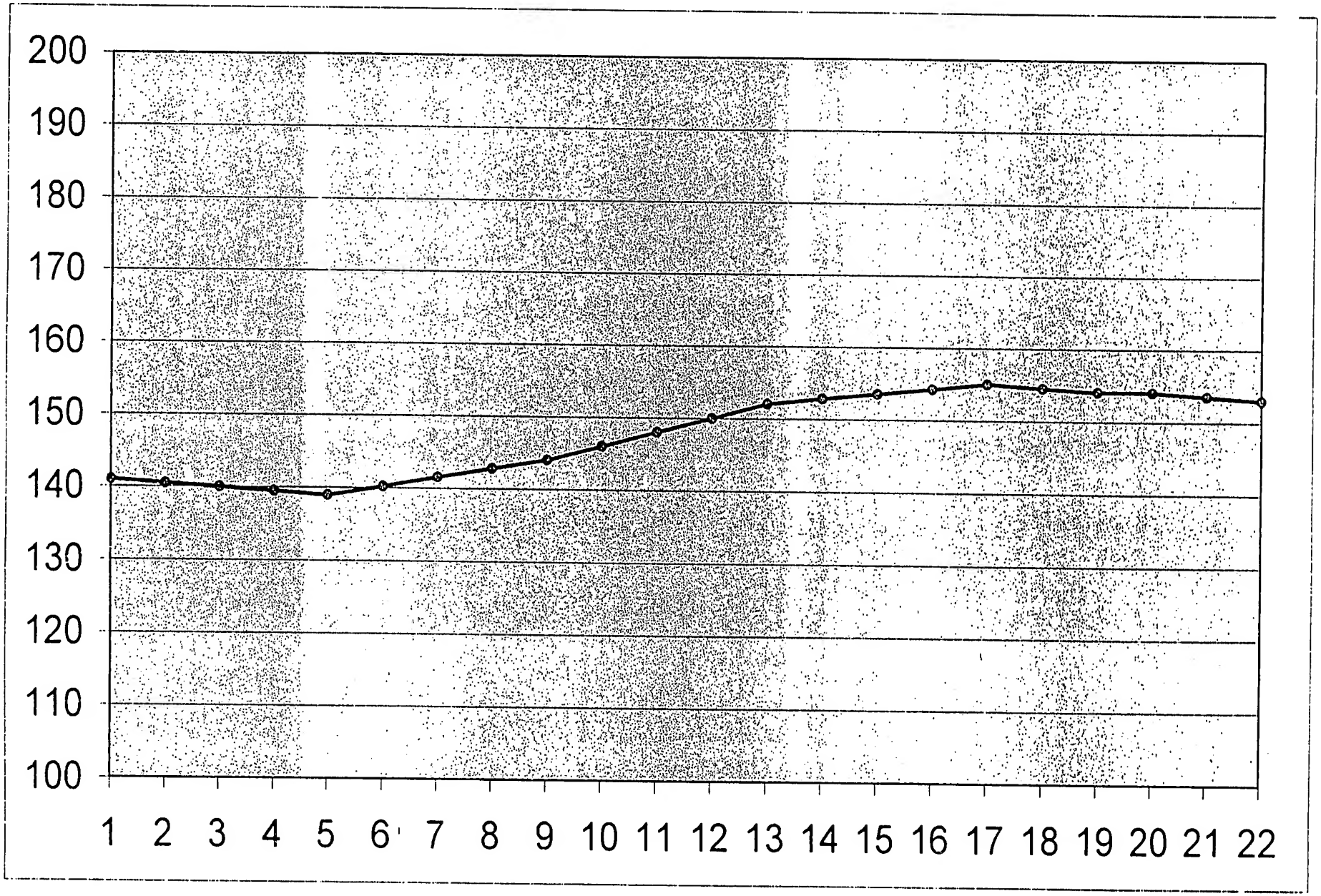

200
190
180
170
160
150
140
130
120
110
100
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22

FIGURE 11

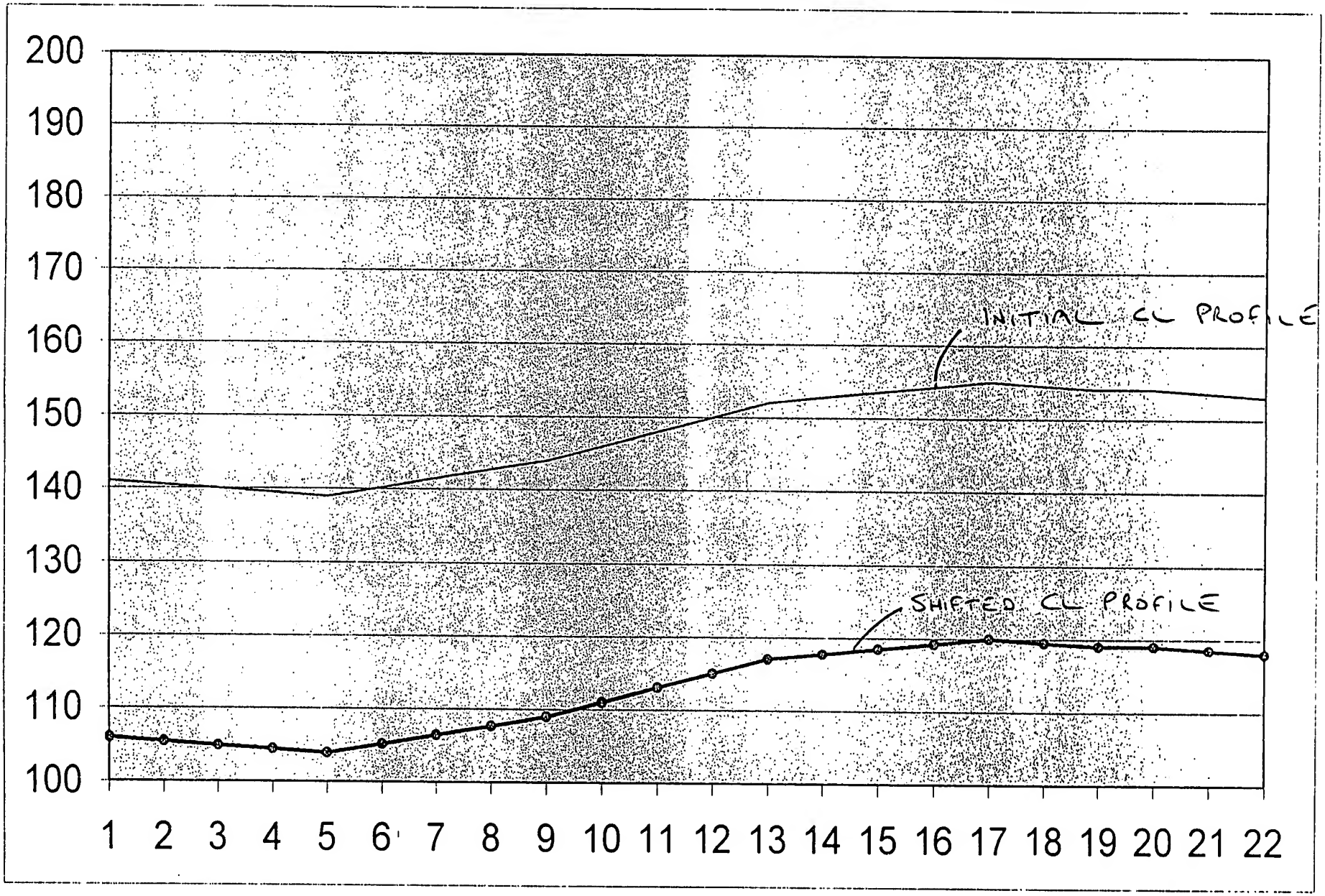

200
190
180
170
160
150
140
130
120
110
100
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22
INITIAL CL PROFILE
SHIFTED CL PROFILE

FIGURE 12

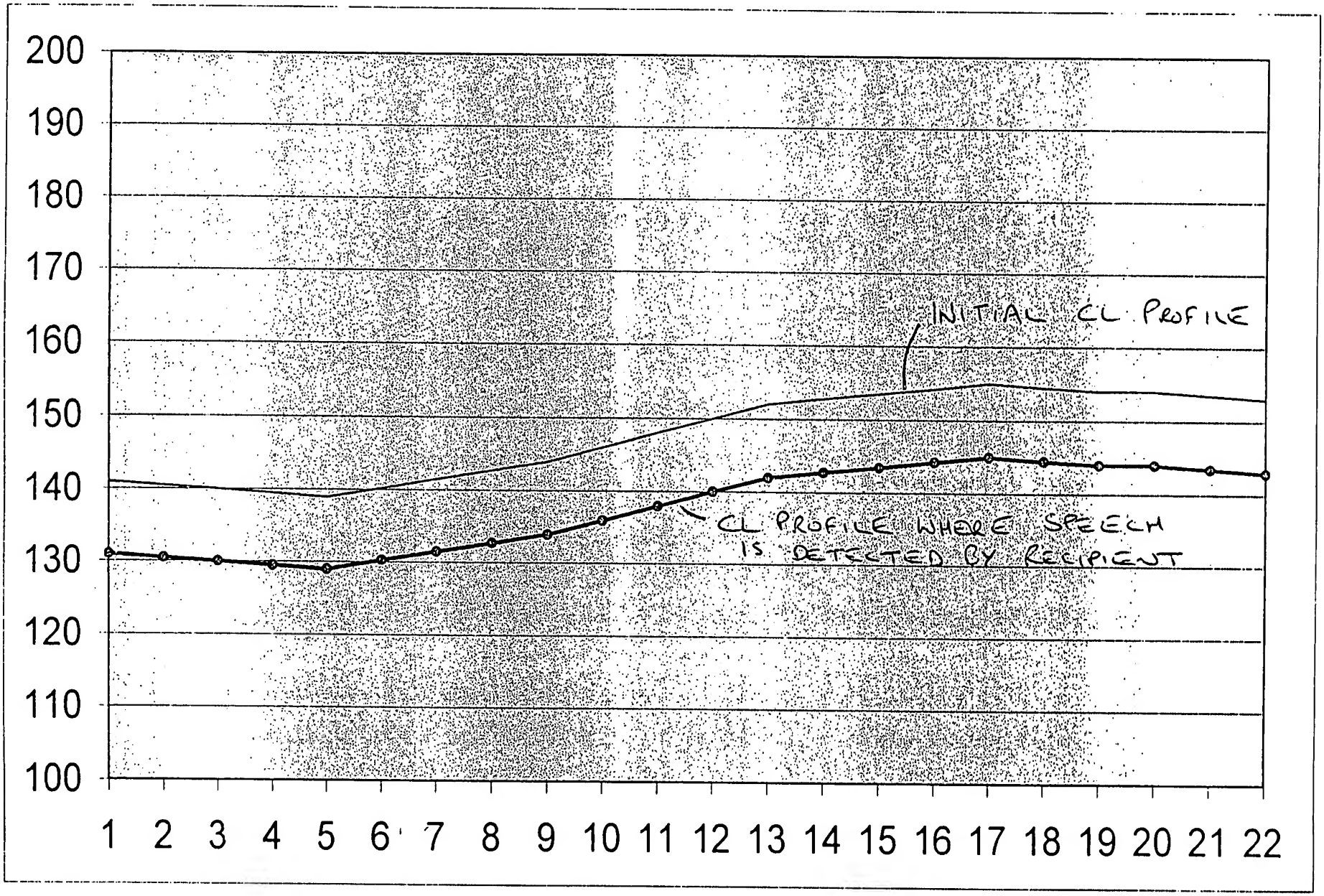

200
190
180
170
160
150
140
130
120
110
100
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22
INITIAL CL PROFILE
CL PROFILE WHERE SPEECH IS DETECTED BY RECIPIENT

FIGURE 13

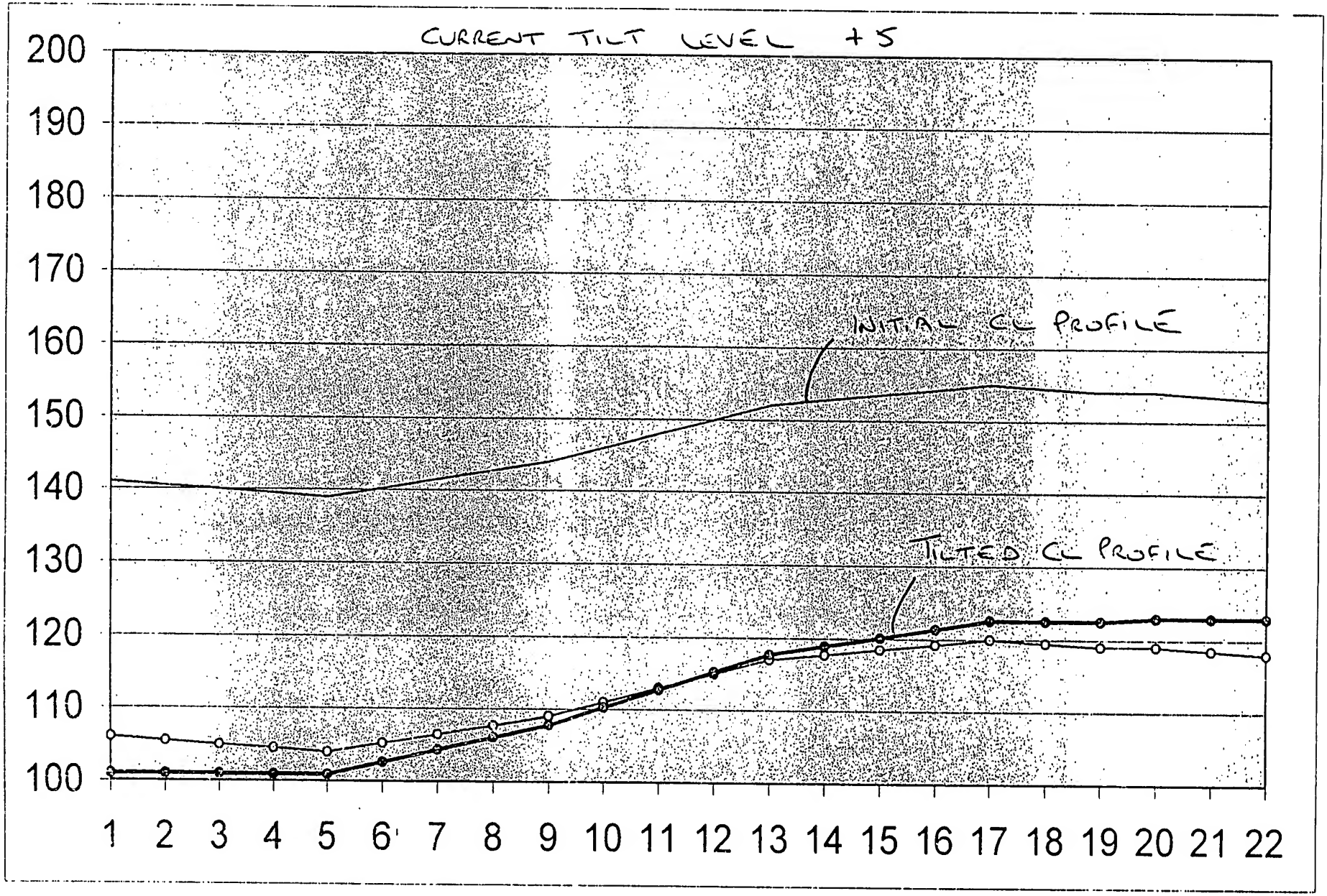

CURRENT TILT LEVEL +5
200
190
180
170
160
150
140
130
120
110
100
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22
INITIAL CL PROFILE
TILTED CL PROFILE

FIGURE 14

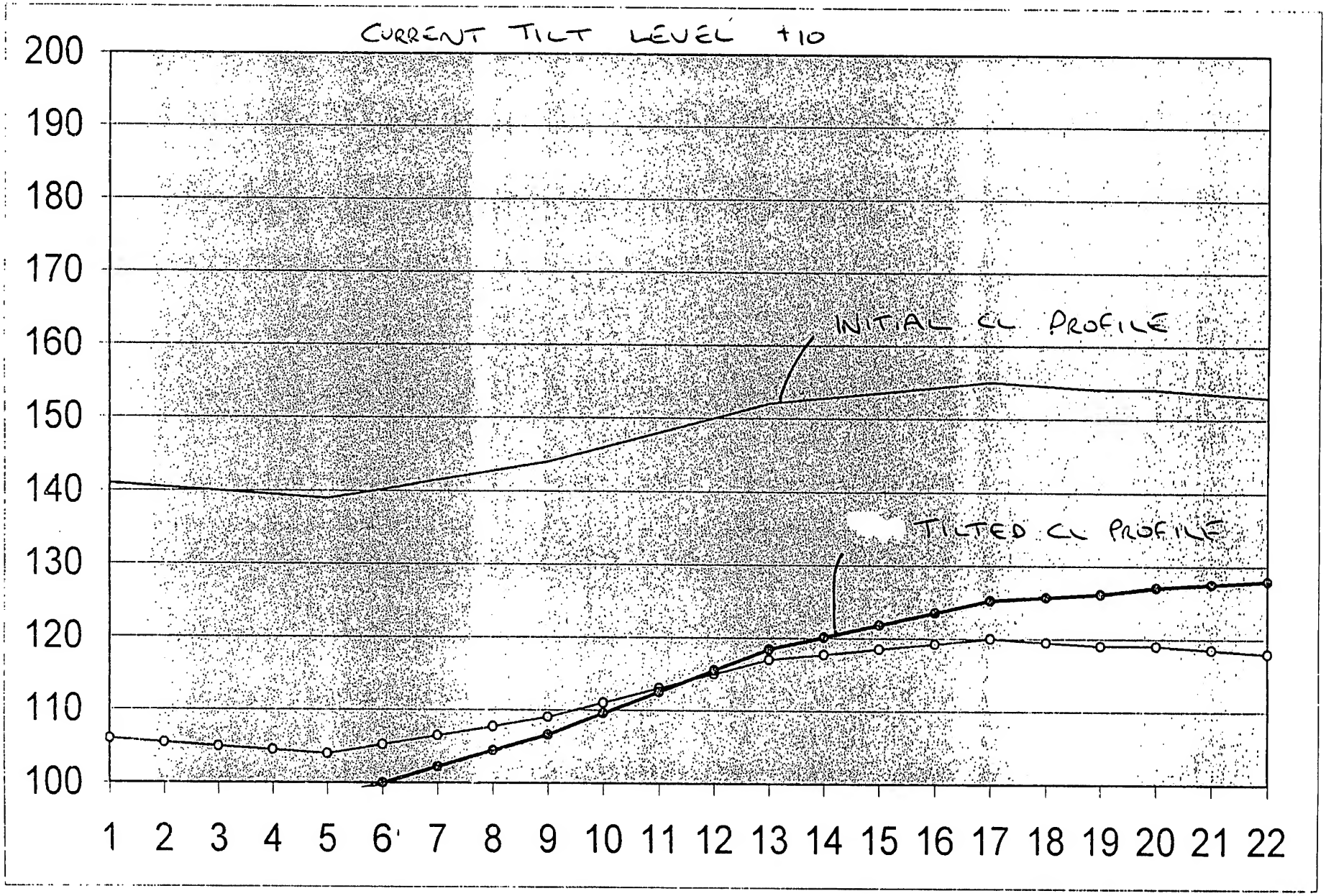

CURRENT TILT LEVEL +10
200
190
180
170
160
150
140
130
120
110
100
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22
INITIAL CL PROFILE
TILTED CL PROFILE

FIGURE 15

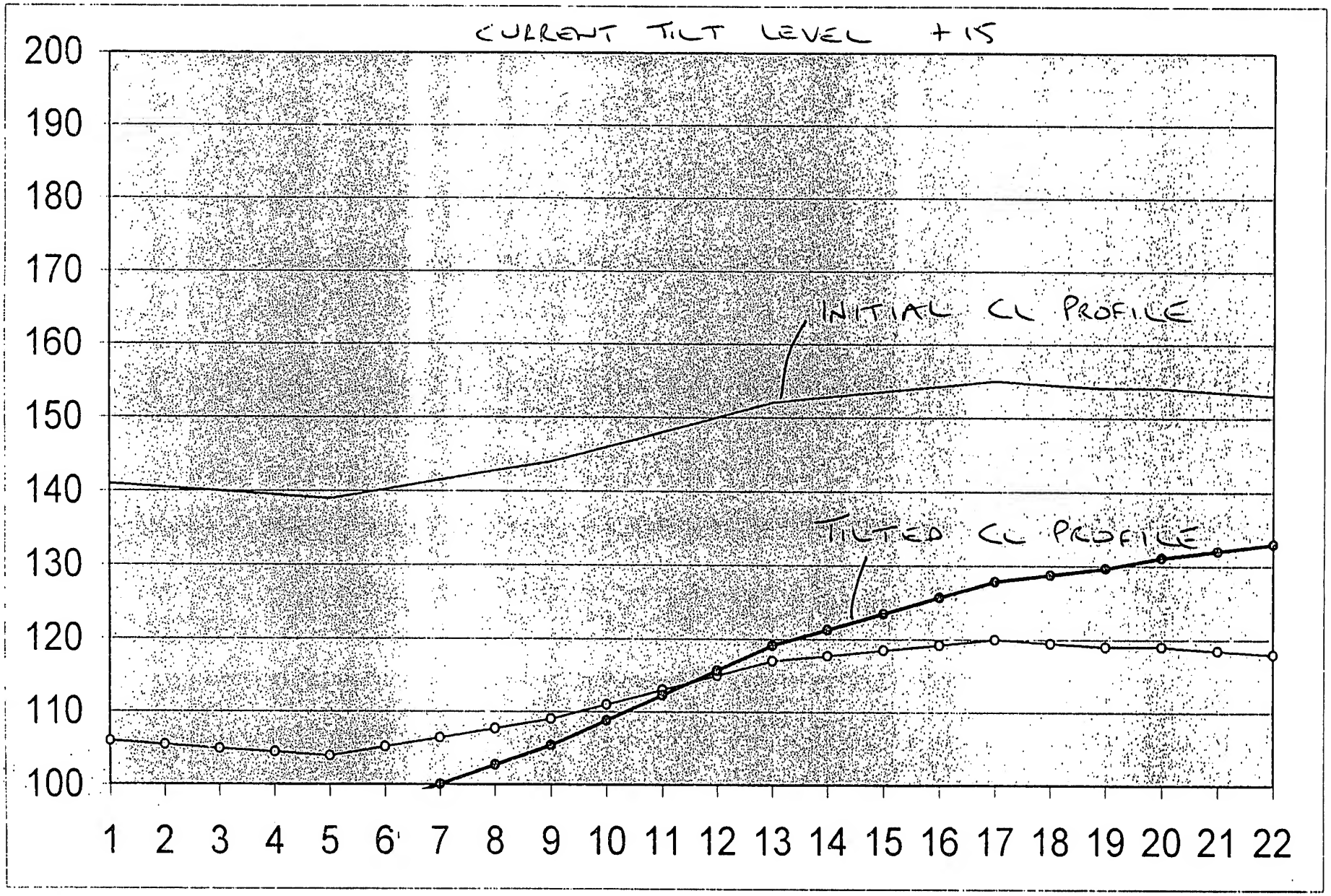

CURRENT TILT LEVEL +15
200
190
180
170
160
150
140
130
120
110
100
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22
INITIAL CL PROFILE
TILTED CL PROFILE

FIGURE 16

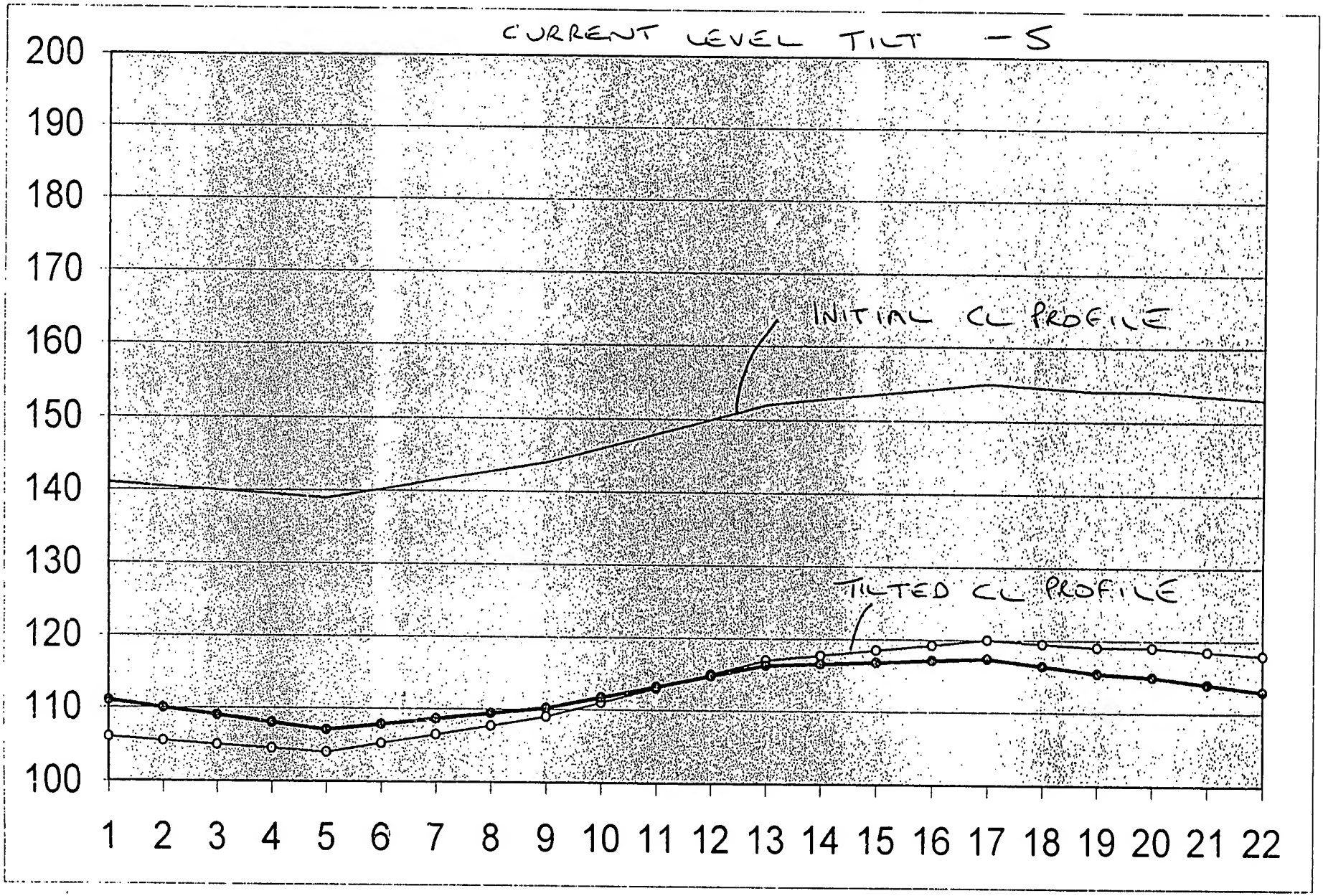

CURRENT LEVEL TILT -5
200
190
180
170
160
150
140
130
120
110
100
INITIAL CL PROFILE
TILTED CL PROFILE
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22

FIGURE 17

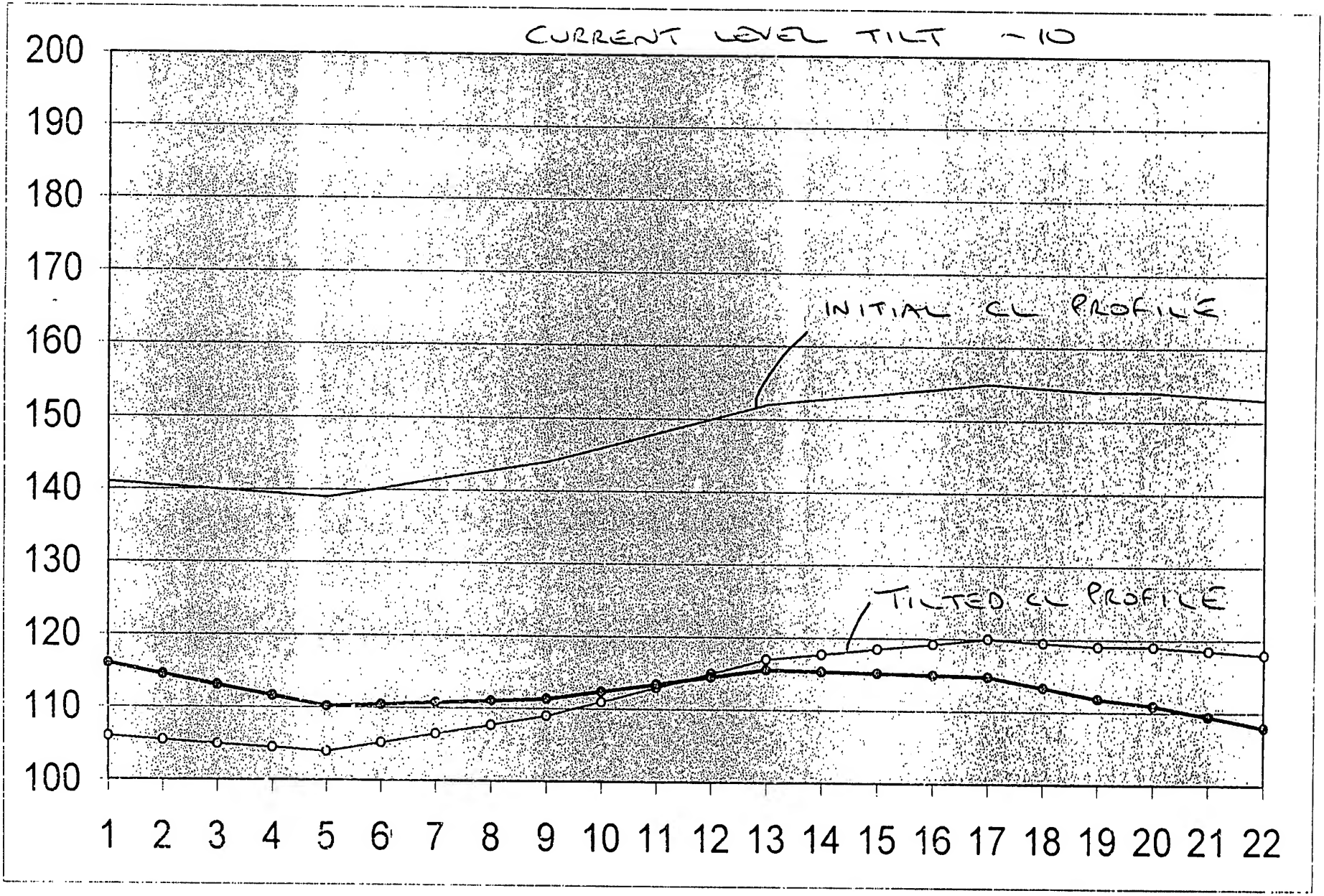
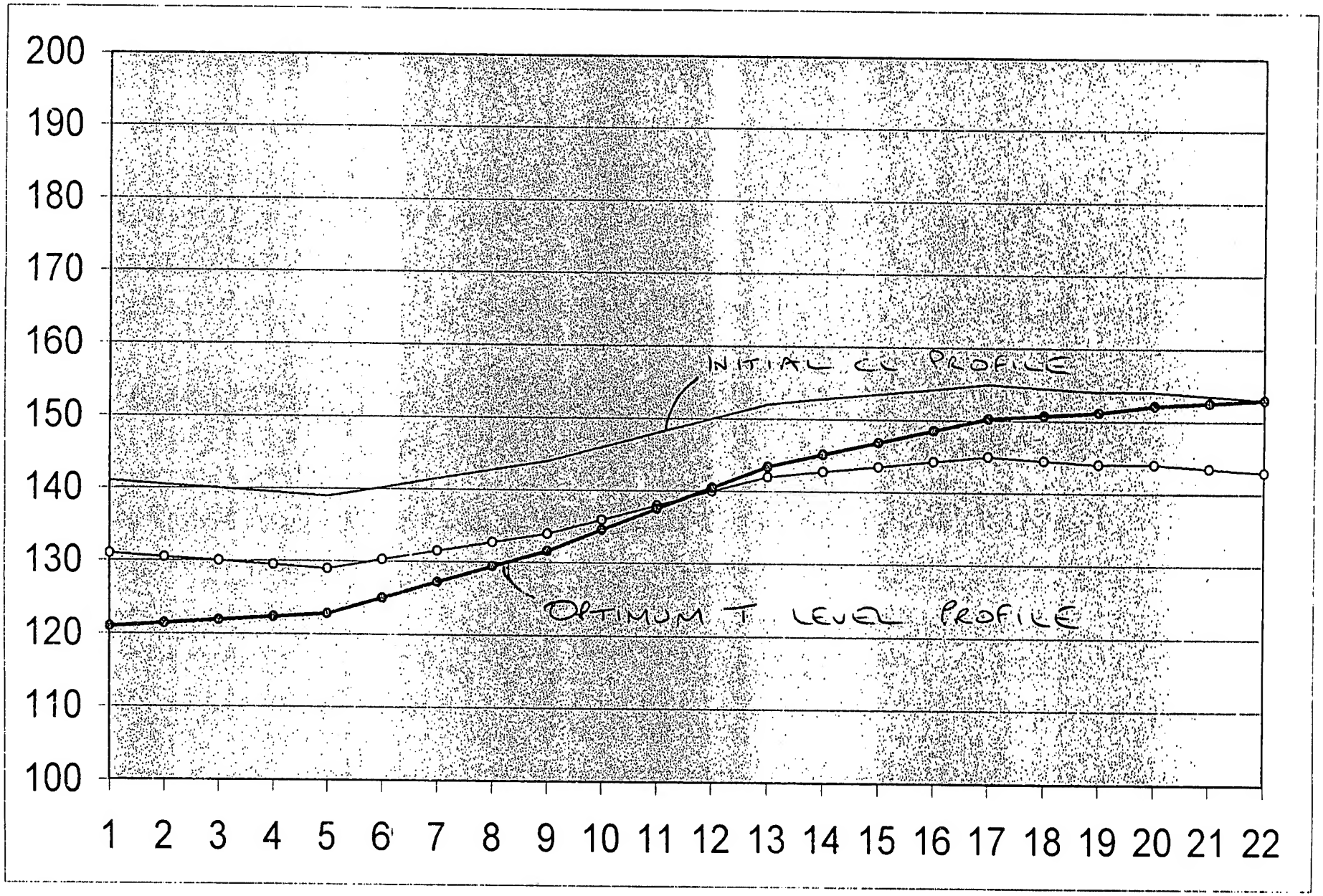

CURRENT LEVEL TILT -10
INITIAL CL PROFILE
TILTED CL PROFILE
200
190
180
170
160
150
140
130
120
110
100
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22

FIGURE 18


200
190
180
170
160
150
140
130
120
110
100
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22
INITIAL CL PROFILE
OPTIMUM T LEVEL PROFILE